



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,598	07/23/2002	Janet Mary Hock	X-13527	9430

25885 7590 09/09/2004

ELI LILLY AND COMPANY  
PATENT DIVISION  
P.O. BOX 6288  
INDIANAPOLIS, IN 46206-6288

EXAMINER
----------

AUDET, MAURY A

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MS  
**Office Action Summary**

Application No.

10/070,598

Applicant(s)

HOCK, JANET MARY

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Response to Amendment/Arguments**

This action is in response to the papers filed 06/04/2004. Claims 1-9 and 14-18 are pending.

### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1-9 and 14-17 under 35 U.S.C. 102(b) as being anticipated by any of WO 92/00753 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA), Aiginger et al. (Oesterreichische Zeitschrift Fuer Onkologie. Vol. 2, no. 1, 1975: 17-24), Trembling et al. (Journal of Endocrinology. Vol. 144, no. Suppl., 1995: P223), and Holick (US 5840690), is maintained for the reasons of record. Applicant's arguments have been fully considered but are not found persuasive. The claim language is not expressly drawn to the subject matter upon which Applicant's arguments are premised. The original claims were drawn to "a method of reducing the risk of cancer in a human subject". The references teach the use of PTH, PTHrP (PTH related protein) 1-34, or human PTH or fragments thereof (e.g. PTH(1-34)) for in vivo (or in vitro studies directed toward future in vivo use) to treat or inhibit cancer or carcinoma. Since every person, either with or without cancer, is at risk for [developing] cancer, than references teachings of treating or inhibiting cancer, nevertheless teaches reducing the risk/risks associated with cancer.

Applicant has now added the limitation that the human subject be "at risk for developing cancer". Applicant has argued that the references do not teach the use of PTH to reduce the risk of cancer in a person who has not yet developed cancer. Similarly, since every human subject is

Art Unit: 1654

“at risk for developing cancer”, even if they have already had cancer (i.e. developing a new cancer lines/carcinomas), then the references still teach the claimed subject matter. The administration of PTH, PTHrP (PTH related protein) 1-34, or human PTH or fragments thereof (e.g. PTH(1-34)) would inherently reduce the risk of cancer in a person at risk for developing cancer, as claimed.

### ***Claim Rejections - 35 USC § 103***

The rejection of claims 1-9 and 14-18 under 35 U.S.C. 103(a) as being unpatentable over WO 92/00753 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA), Aiginger et al. (Oesterreichische Zeitschrift Fuer Onkologie. Vol. 2, no. 1, 1975: 17-24), Trembling et al. (Journal of Endocrinology. Vol. 144, no. Suppl., 1995: P223), and Holick (US 5840690) in view of Bishop et al. (US 5972917), is maintained for the reasons of record. Applicant's arguments have been fully considered but are not found persuasive. As discussed above, the references still teach, and thus suggest under § 103, the use of PTH or PTH agonists/related peptides that intrinsically reduce the risk of cancer as a result of being administered for the treatment of cancer (and the rejection of claim 18 remains obvious in view of Bishop et al.).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1654

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA  
9/3/04

  
CHRISTOPHER R. TATE  
PRIMARY EXAMINER